CERTARA

6500 Narratives in 6 Weeks

Background

This top-20 biopharmaceutical company specializes in the discovery, development, manufacturing, and marketing of medications, with a focus on oncology, cardiovascular and metabolic disease, respiratory, inflammation and autoimmunity.

Synchrogenix has been working with this global, top-20 biopharmaceutical company for 10 years. In that time, Synchrogenix has been contracted to support many therapeutic areas, namely diabetes, emerging psychiatry, central nervous system, cardiovascular and oncology. Services offered span the product's life cycle from early phase development through post-approval, regulatory defense activities, drug safety, and life cycle management, including ad hoc requests, such as bridging documents and regional payer submissions.

Challenge

Recently, Synchrogenix was approached by this sponsor to write 6500 narratives in six weeks, based on a post-approval request from the health authorities. A customized process was required to execute the writing, quality control, and medical review of the narratives on time and in compliance with the regulatory agency requirements.

Solution

Synchrogenix collaborated with the sponsor's team to establish a process for populating, revising, and finalizing the narratives. A trial run of the process was conducted to ensure efficiency and alignment on expectations. Staff members were then trained on the process once it was established.

To meet the tight timelines, Synchrogenix leveraged its seven global offices, using the variation in time zones to deliver an around-the-clock solution. Narratives were delivered to the sponsor in batches for simultaneous and continual writing, review, and publishing. A log was maintained on a real-time basis to inform both parties of the status of each narrative batch and of any issues that required reconciliation.

Challenge

To deliver 6500 high-quality narratives while meeting timeline and budget.

Solution

Leverage expertise and capacity to establish a process and deliver on time.

Benefit

The sponsor met the health authority request without repercussions. The sponsor now also has a process in place should another similar request be issued in the future.

Synchrogenix delivered a high-quality, complete, and compliant product, while meeting the timeline and budget.

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About Certara

Certara is a leading provider of decision support technology and consulting services for optimizing drug development and improving health outcomes. Certara's solutions, which span the drug development and patient care lifecycle, help increase the probability of regulatory and commercial success by using the most scientifically advanced modeling and simulation technologies and regulatory strategies. Its clients include hundreds of global biopharmaceutical companies, leading academic institutions and key regulatory agencies.

For more information visit www.certara.com or email sales@certara.com.

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